

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

BRAINTREE LABORATORIES, INC.,

Plaintiff,

v.

CYPRESS PHARMACEUTICAL, INC.,

Defendant.

Civil Action No. 12-cv-6851-AJN  
ECF Case

**PLAINTIFF BRAINTREE LABORATORIES INC.'S OPPOSITION TO  
DEFENDANT CYPRESS PHARMACEUTICAL, INC.'S MOTION FOR  
SUMMARY JUDGMENT OF NONINFRINGEMENT**

## TABLE OF CONTENTS

Table of Authorities .....	ii
I. INTRODUCTION .....	1
II. STATEMENT OF FACTS .....	1
A. Background of this Litigation .....	1
B. The '149 Patent and the Invention of SUPREP .....	2
C. SUPREP Bowel Prep Kit .....	3
D. Cypress' Proposed Generic Copy of SUPREP .....	3
E. The Novel Litigation .....	4
III. ARGUMENT .....	5
A. Legal Standard .....	5
1. Summary Judgment of Noninfringement Under §271(e)(2) .....	5
B. Cypress' Proposed Generic Copy of SUPREP Infringes the "about 100ml to about 500ml" limitation of the Claims of the '149 Patent .....	7
C. Cypress' Motion Relies on an Improper Reading of the Claims .....	10
1. Cypress Ignores the Claim Limitation "for inducing purgation" .....	10
2. Claims Must be Read from the Perspective of a Person of Ordinary Skill in the Art of the '149 Patent, Not That of Cypress' Attorneys .....	11
3. Cypress Seeks to Import a Nonexistent "Colon Cleansing" Limitation into the Claims .....	12
4. Cypress' Reading of the Claim Improperly Renders the Claim Limitation "for inducing purgation" Meaningless .....	14
5. Cypress Improperly Attempts to Reargue the Claim Construction of "Purgation" .....	15
D. Cypress' Noninfringement Argument Relies on a Mischaracterization of its Proposed Generic Copy of SUPREP and its Proposed Indication .....	15
E. Cypress' Misapprehends Infringement Under §271(e) .....	17
F. Judge Sheridan Properly Defined Novel's Accused Product .....	18
G. Braintree's Infringement Argument Does Not Improperly Divide the Accused Product .....	19
H. Cypress' Assertion that Purgation is an "Off-Label" Use Lacks Merit .....	20
1. The Cases Cypress Cites Are Inapposite .....	21
2. Judge Sheridan Rejected Cypress' On-/Off-Label Argument in the <i>Novel Case</i> .....	24
IV. CONCLUSION .....	25

## TABLE OF AUTHORITIES

	Page(s)
<b>CASES</b>	
<i>Accent Packaging, Inc. v. Leggett &amp; Platt, Inc.</i> , 707 F.3d 1318 (Fed. Cir. 2013).....	7, 8, 11, 20
<i>Acumed LLC v. Stryker Corp.</i> , 483 F.3d 800 (Fed. Cir. 2007).....	6
<i>Allergan v. Alcon Labs.</i> , 324 F.3d 1322 (Fed. Cir. 2003).....	22, 23, 25
<i>AstraZeneca LP v. Apotex, Inc.</i> , 633 F.3d 1042 (Fed. Cir. 2010).....	7, 9, 22, 25
<i>Bayer AG v. Elan Pharm. Research Corp.</i> , 212 F.3d 1241 (Fed. Cir. 2000).....	17, 23, 24
<i>Bayer Schering Pharma AG v. Lupin, Ltd.</i> , 676 F.3d 1316 (Fed. Cir. 2012).....	22, 23, 25
<i>Douglas Dynamics, LLC v. Buyers Prods. Co.</i> , 717 F.3d 1336 (Fed. Cir. 2013).....	14
<i>Dow Chem. Co. v. NOVA Chem. Corp.</i> , 629 F. Supp. 2d 397 (D. Del. 2009).....	19, 20
<i>DSU Med. Corp. v. JMS Co.</i> , 471 F.3d 1293 (Fed. Cir. 2006).....	7
<i>Ecolab, Inc. v. Envirochem, Inc.</i> , 264 F.3d 1358 (Fed. Cir. 2001).....	19
<i>Eli Lilly &amp; Co. v. Medtronic, Inc.</i> , 496 U.S. 661 (1990).....	18
<i>Estee Lauder Inc. v. L'Oreal, S.A.</i> , 129 F.3d 588 (Fed. Cir. 1997).....	12
<i>Falana v. Kent State Univ.</i> , 669 F.3d 1349 (Fed. Cir. 2012).....	13
<i>Glaxo, Inc. v. Novopharm, Ltd.</i> , 110 F.3d 1562 (Fed. Cir. 1997).....	6, 17, 18
<i>Halliburton Energy Svcs., Inc. v. M-I LLC</i> , 514 F. 3d 1244 (Fed. Cir. 2008).....	10

<i>Innova/Pure Water, Inc. v. Safari Water Filtration Sys.</i> , 381 F.3d 1111 (Fed. Cir. 2004).....	13
<i>Jeneric/Pentron, Inc. v. Dillon Co.</i> , 205 F.3d 1377 (Fed. Cir. 2000).....	19, 20
<i>Mangosoft, Inc. v. Oracle Corp.</i> , 525 F.3d 1327 (Fed. Cir. 2008).....	14
<i>Matsushita Elec. Indus. Co. v. Zenith Radio Corp.</i> , 475 U.S. 574 (1986).....	5
<i>Novartis Pharms. Corp. v. Apotex Corp.</i> , No. 02CIV.8917 (KMW)(HBP), 2006 WL 626058 (S.D.N.Y. Mar. 13, 2006).....	19
<i>Perkin-Elmer Corp. v. Westinghouse Elec. Corp.</i> , 822 F.2d 1528 (Fed.Cir.1987).....	20
<i>Phillips v. AWH Corp.</i> , 415 F.3d 1303 (Fed. Cir. 2005) (en banc).....	11, 12
<i>Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.</i> , 655 F.3d 1364 (Fed. Cir. 2011).....	6
<i>Sundance, Inc. v. DeMonte Fabricating Ltd.</i> , 550 F.3d 1356 (Fed. Cir. 2008).....	11, 12
<i>Unique Concepts, Inc. v. Brown</i> , 939 F.2d 1558 (Fed. Cir. 1991).....	7, 8, 11, 20
<i>Warner-Lambert Co. v. Apotex Corp.</i> , 316 F.3d 1348 (Fed. Cir. 2003).....	<i>passim</i>

#### STATUTES

21 U.S.C. § 355(b)(i) .....	1
35 U.S.C. §156.....	2
35 U.S.C. § 271 .....	6
35 U.S.C. § 271(a) .....	6, 18
35 U.S.C. § 271(b) .....	6
35 U.S.C. § 271(e) .....	2, 17, 18
35 U.S.C. §271(e)(2).....	5, 6, 18

21 U.S.C. §355.....	17
---------------------	----

**RULES**

Fed. R. Civ. P. 56(a) .....	5
-----------------------------	---

## **I. INTRODUCTION**

In its Motion, defendant Cypress Pharmaceutical, Inc. (“Cypress”) misstates and ignores the relevant claim language of U.S. Patent No. 6, 946, 149 (“the ’149 patent”), attempts to import claim limitations where they do not exist, misapplies the relevant law, relies on irrelevant law, and mischaracterizes the very product it seeks to market. Based on these misstatements, Cypress asks this Court to depart from the findings of fact and conclusions of law U.S. District Judge Peter Sheridan made over the course of nearly two years in *Braintree Laboratories, Inc. v. Novel Laboratories, Inc.*, D.N.J., C.A. No. 11-1341 (“the *Novel Case*”)—litigation involving the *same* product (Braintree’s SUPREP® Bowel Prep Kit (“SUPREP”)), the *same* patent, and, in all relevant respects, the same generic copy of SUPREP. For the reasons stated below, Cypress’ motion should be denied.

## **II. STATEMENT OF FACTS**

### **A. Background of this Litigation**

Braintree holds New Drug Application No. 22372 for SUPREP, which is FDA-approved for “cleansing of the colon in preparation for colonoscopy in adults.” *See* SF 1, 4<sup>1</sup>; BMF 12, 15.<sup>2</sup> The FDA approved SUPREP on August 5, 2010 after substantial research and development, and extensive clinical trials by Braintree. *See* SF 2; BMF 13, 45. Pursuant to 21 U.S.C. § 355(b)(i), SUPREP is listed in the FDA’s *Approved Drug Products with Therapeutic Equivalence Evaluations* as being covered by one or more claims of Braintree’s ’149 patent.<sup>3</sup> BMF 14-18.

On March 15, 2012, Cypress submitted Abbreviated New Drug Application (“ANDA”)

---

<sup>1</sup> All references to “SF” are to the Stipulated Facts for Purposes of Cypress’ Motion for Summary Judgment of Noninfringement, which was submitted to this Court via e-mail in support of Cypress’ Motion for Summary Judgment on July 15, 2013 and is also attached as Exhibit 11 to the Declaration of Jennifer Brown in Support of Braintree’s Opposition to Cypress’ Motion for Summary Judgment of Noninfringement (“Brown Declaration”), filed concurrently herewith.

<sup>2</sup> All references to “BMF” are to Braintree’s Counter-Statement of Material Facts in Support of Its Opposition to Cypress’ Motion for Summary Judgment of Noninfringement, filed concurrently herewith.

<sup>3</sup> *See* [http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl\\_No=022372&Product\\_No=001&table1=OB\\_Rx](http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl_No=022372&Product_No=001&table1=OB_Rx).

No. 204135 seeking approval to market a generic copy of SUPREP before expiration of the '149 patent. *See* SF 9, 10; BMF 18, 35, 37, 39. On July 31, 2012, Cypress sent Braintree a Paragraph IV letter stating that, in Cypress' view, the claims of the '149 patent are invalid or not infringed by its proposed generic copy of SUPREP. BMF 36, 39. On September 11, 2012, Braintree filed this case against Cypress for enforcement of the '149 patent pursuant to 35 U.S.C. § 271(e). BMF 1, 12, 16, 18, 50.

For purposes of opposing Cypress' motion, Braintree asserts that Cypress and its proposed generic copy of SUPREP infringe claims 15, 18, 19, 20 and 23 of the '149 patent. Cypress has agreed not to "advance[e] in this case any other noninfringement defenses" other than that based on the "from about 100 ml to about 500 ml" limitation in the asserted claims. Ex. 1, at 10:7-13; Dkt. 41, ¶ 3, 6.<sup>4</sup> If the Court denies Cypress' motion, "Cypress stipulates that its proposed generic version of Braintree's SUPREP described in Cypress' ANDA No. 204135 ... infringes claims 15, 18, 19, 20, and 23 of the '149 Patent." *See id.* ¶ 3; *see also* BMF 100; Ex. 1, at 10:7-13 ("we are either right on the issue that you do not need to construe purgation, or we lose; that is, you find that there is infringement.").

## **B. The '149 Patent and the Invention of SUPREP**

The '149 patent was filed on August 30, 2002 and issued on September 20, 2005.<sup>5</sup> BMF 2-4. It expires no earlier than March 7, 2023.<sup>6</sup> BMF 18. The '149 patent discloses and claims the discovery by Dr. John Fordtran and Dr. Mark Cleveland that low-volume, balanced formulations of poorly-absorbable sulfate salts could induce purgation of the colon while avoiding clinically significant electrolyte shifts in patients. Dkt. 46-4, at Col. 4:58-5:7; BMF 5-

---

<sup>4</sup> References in this document to "Ex." refer to exhibits to the Brown Declaration, filed concurrently herewith.

<sup>5</sup> On June 30, 2009, the United States Patent & Trademark Office ("PTO") again confirmed the patentability of the '149 patent after Braintree voluntarily requested that the PTO reexamine the '149 patent in view of newly identified prior art. *See* Ex. 3 at BRTSUP00000622-39; Ex. 4 at BRTSUP00000471-76; Dkt. 46-3.

<sup>6</sup> Braintree has applied for a patent term extension pursuant to 35 U.S.C. §156. If granted, the '149 patent will expire on August 5, 2024.

6. Through a unique and novel combination of sulfate salts in an aqueous (water-based) hypertonic solution, the claimed compositions of the '149 patent induce purgation while avoiding dangerous electrolyte abnormalities caused by the sodium phosphate-based prior art solutions, which in certain cases resulted in dangerous side effects including heart and kidney failure as well as death. *See* Ex. 6; *see also* Dkt. 46-15, at 2-3; BMF 6, 11.

### C. SUPREP Bowel Prep Kit

Braintree makes and sells SUPREP as a kit containing two 6-ounce bottles of an aqueous hypertonic solution of potassium sulfate, magnesium sulfate, and sodium sulfate.<sup>7</sup> Ex. 10, BMF 19, 22, 26-27, 82. The FDA-approved label for SUPREP instructs patients to take the product according to the following *two-step dosing regimen* to achieve the goal of colon cleansing in preparation for a colonoscopy (*see* Ex. 10, at BRTSUP00000130):

- First, the patient is directed to consume one 6-ounce bottle of SUPREP diluted with 10 ounces of water—for a total of 16 ounces (473ml). *See id.* Consumption of that first bottle will induce the patient to have a purgation, *i.e.*, an evacuation of a copious amount of stool from the bowels after oral administration of the solution. *See id.* at BRTSUP00000136 (“[t]he osmotic effect of the unabsorbed ions, when ingested with a large volume of water, produces a copious watery diarrhea”); SF 7; BMF 21-25; Dkt. No. 41, at ¶5; Ex. 6, at 11.
- Second, after waiting 10-12 hours, the patient is directed to consume a second 6-ounce bottle of SUPREP diluted with 10 ounces of water—again totaling 473ml. *See* Ex. 10, at BRTSUP00000130. Consumption of this second bottle will induce the patient to have another purgation. *See id.* at BRTSUP00000136; SF 6, 7, 8; BMF 28-32.
- Ingestion of both bottles, 10-12 hours apart, helps to achieve the goal of adequate cleansing of the colon for colonoscopy procedures. *See id.* at BRTSUP00000130; SF 8; BMF 24, 33.

### D. Cypress’ Proposed Generic Copy of SUPREP

Cypress’ proposed generic product, described in Cypress’ ANDA No. 204135, is a copy of SUPREP. SF 11, 12. It is bioequivalent, pharmaceutically equivalent, and therapeutically equivalent to SUPREP. SF 14-20; BMF 38, 40, 42-48. Like SUPREP, it is an osmotic laxative,

---

<sup>7</sup> In a declaration filed concurrently herewith, Dr. David Peura explains how SUPREP works and how it is different from other colonoscopy prep products. *See* Peura Decl., ¶¶ 27-55. Citations to “Peura Decl.” refer to the Declaration of David A. Peura, M.D. in Support of Braintree’s Opposition to Cypress Motion for Summary Judgment of Noninfringement, filed concurrently herewith.

and contains sodium sulfate, potassium sulfate, and magnesium sulfate at the same concentration levels as SUPREP. SF 17-19; BMF 41, 46-48. The proposed label for Cypress' proposed generic copy of SUPREP is, in all relevant and material respects, the same as Braintree's FDA-approved label for SUPREP. SF 28-30; BMF 59. Cypress' proposed generic product will, if approved, have the same indication as SUPREP: cleansing of the colon in preparation for colonoscopy in adults. SF 4, 20; BMF 15, 49.

#### **E. The Novel Litigation**

Cypress is not the first ANDA filer seeking to market a generic copy of SUPREP. In January 2011, after receiving a Paragraph IV letter from Novel Laboratories, Inc. ("Novel"), Braintree sued Novel for patent infringement in the U.S. District Court for the District of New Jersey ("the *Novel Case*"). Judge Sheridan was assigned, and ultimately decided, the case. BMF 78, 80.

During two years of litigation in the *Novel Case*, Judge Sheridan addressed, among other issues, claim construction, infringement, and validity of the '149 patent.<sup>8</sup> *See generally* Ex. 6; Dkt. 46-15; Ex. 5; BMF 81-99. Judge Sheridan found that Novel's proposed generic copy of SUPREP—a product that Cypress admits "is, in all relevant and material respects, identical to Novel's proposed generic copy of SUPREP"—infringes the claims of the '149 patent and that its proposed label induces infringement.<sup>9</sup> *See* Dkt. 46-15 (*Novel Case* Summary Judgment Opinion); *See* Dkt. No. 41, at ¶7 (Joint Procedural Stipulation); BMF 79, 87-99. Following a six-day trial, Judge Sheridan concluded that the '149 patent was valid. *See* Ex. 5.

---

<sup>8</sup> Judge Sheridan construed four disputed claim terms in the '149 patent after full briefing on claim construction, totaling nearly 120 pages, and over 100 pages of expert declarations, and a 2-day *Markman* hearing during which he heard a technology tutorial delivered by the '149 patent inventors, lengthy testimony from three expert witnesses, and argument. *See* Ex. 6 (*Novel Case*, Dkt. No. 130, Order on Claim Construction).

<sup>9</sup> Judge Sheridan made his decision after considering full briefing on Braintree's Motion for Summary Judgment of Infringement, full briefing on Novel's Motion for Summary Judgment of Noninfringement, and oral argument on those two motions. *See Novel Case*, Dkt. Nos. 143, 159, 173, 176, 203, 207; Dkt. 46-15 (*Novel Case* Summary Judgment Opinion). Judge Sheridan later confirmed his finding of infringement when he denied Novel's Motion for Reconsideration. *See* Ex. 12 (*Novel Case* Order Denying Motion for Reconsideration).

In reaching the conclusion that the '149 patent was valid and infringed by Novel's proposed generic product, Judge Sheridan addressed—and rejected—the same arguments Cypress makes in its motion:

- Judge Sheridan rejected Novel's claim construction argument that the term "purgation" means "cleansing." He reasoned that the claims of the '149 patent are not directed to "cleansing" because "the term 'cleanse' is never used in the language of claims 15 and 18." "Hence, when enumerating the claims, the inventors were being more precise with their use of 'purgation.'" *See* Ex. 6, at 6; BMF 84.
- Judge Sheridan rejected Novel's attempt to import a cleansing limitation into the claims of the '149 patent from alleged "admissions" in the file history. He reasoned that "these alleged admissions do nothing to contradict the fact that . . . one bottle of SUPREP is sufficient to cause purgation of the colon." *See* Dkt. 46-15, at 16-17; BMF 94.
- Judge Sheridan rejected Novel's noninfringement argument based on *Warner-Lambert* and its progeny. He found that Novel's argument was "without merit...[b]ecause purgation is the method by which SUPREP achieves the FDA-approved indication of colon cleansing, [and therefore] purgation cannot be an off-label use for SUPREP." *See* Dkt. 46-15, at 16; BMF 96.

Judge Sheridan entered final judgment in favor of Braintree and enjoined Novel from making, using or selling its proposed generic copy of SUPREP. *See* Ex. 7. The *Novel Case* is now on appeal before the United States Court of Appeals for the Federal Circuit.

### **III. ARGUMENT**

#### **A. Legal Standard**

##### **1. Summary Judgment of Noninfringement Under §271(e)(2)**

Summary judgment is appropriate only if Cypress can show that "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). Cypress bears the burden of proving that no genuine issue of material fact exists. *See Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 n. 10 (1986). To carry its burden on its motion, Cypress must demonstrate that there is no genuine dispute as to any material fact that its proposed generic copy of SUPREP does not infringe the '149 patent.

The infringement analysis under 35 U.S.C. §271(e)(2) in the ANDA context is the same

as a “traditional” infringement analysis under 35 U.S.C. §271(a). *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1365 (Fed. Cir. 2003). Section 271(e)(2) “simply provides an ‘artificial’ act of infringement that creates case-or-controversy jurisdiction to enable the resolution of an infringement dispute before the ANDA applicant has actually made or marketed the proposed product.” *Id.* “Notwithstanding this defined act of infringement, a district court’s inquiry in a suit brought under § 271(e)(2) *is the same* as it is in any other infringement suit.” *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997) (emphasis added). The relevant inquiry is “whether the patentee has proven by a preponderance of the evidence that the alleged infringer will likely market an infringing product. What is likely to be sold, or, preferably, what will be sold, will ultimately determine whether infringement exists.” *Glaxo*, 110 F.3d at 1570.

Whether a product is infringing under 35 U.S.C. § 271 is determined through a two-step analysis. “[F]irst, the court determines the meaning of the disputed claim terms, then the accused device is compared to the claims as construed to determine infringement.” *Acumed LLC v. Stryker Corp.*, 483 F.3d 800, 804 (Fed. Cir. 2007) (citation omitted). “To prove infringement, a plaintiff must prove the presence of each and every claim element or its equivalent in the accused method or device.” *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 655 F.3d 1364, 1378 (Fed. Cir. 2011). A person directly infringes § 271(a) if that person makes, uses, offers to sell, or sells any patented invention, within the U.S., or imports into the U.S. any patented invention, without authorization of the patent holder. Direct infringement may be either literal or under the doctrine of equivalents.<sup>10</sup>

A party may indirectly infringe a patent under 35 U.S.C. § 271(b) by inducing another party to make, use, offer to sell, or sell a patented invention in the United States. *See* 35 U.S.C.

---

<sup>10</sup> For purposes of only responding to Cypress’ motion, Braintree does not allege that Cypress’ proposed generic product infringes under the doctrine of equivalents. Braintree otherwise reserves its rights to contend that the doctrine of equivalents may be applied to Cypress’ proposed product to find infringement.

§ 271(b). This requires a showing of specific intent to induce the infringement. *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006). Intent to induce infringement is established where an accused infringer advertises or provides instructions promoting the infringing use. *See AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1059-60 (Fed. Cir. 2010) (finding specific intent to promote infringement based on product label directing consumers to practice the claimed method).

**B. Cypress' Proposed Generic Copy of SUPREP Infringes the "about 100ml to about 500ml" limitation of the Claims of the '149 Patent**

Having agreed to present no other defenses or arguments (*see* Dkt. 41, ¶ 3), Cypress' sole noninfringement argument is that its proposed generic copy of SUPREP does not meet the "about 100 ml to about 500 ml" limitation of the asserted composition (reexamined claims 15 and 18) and method claims (claims 19, 20, and 23) of the '149 patent. Cypress is wrong as a matter of fact and law.

As an initial matter, Cypress' noninfringement argument is premised on a legally improper reading of the asserted claims—one that ignores the claim language as a whole and divorces the functional limitation "*for* inducing purgation" from the "about 100 ml to about 500 ml" limitation for the claimed compositions. *See Accent Packaging, Inc. v. Leggett & Platt, Inc.*, 707 F.3d 1318, 1327 (Fed. Cir. 2013) (rejecting infringement argument because it would render claim limitation "meaningless"); *Unique Concepts, Inc. v. Brown*, 939 F.2d 1558, 1562 (Fed. Cir. 1991) ("All the limitations of a claim must be considered meaningful").

For example, re-examined claim 15 of the '149 patent claims:

***A composition for inducing purgation of the colon of a patient, the composition comprising from about 100 ml to about 500 ml of an aqueous hypertonic solution*** comprising an effective amount of Na<sub>2</sub>SO<sub>4</sub>, and effective amount of MgSO<sub>4</sub>, and an effective amount of K<sub>2</sub>SO<sub>4</sub>, wherein the composition does not produce any clinically significant electrolyte shifts and does not include phosphate.

See Dkt. 46-3, at Claim 15 (emphasis added); *see also id.* at Claim 18. This claim, as construed by Judge Sheridan, requires a composition of about 100 ml to about 500 ml “for inducing purgation;” that is, a composition of no more than about 500 ml and no less than about 100 ml for inducing “an evacuation of a copious amount of stool from the bowels after oral administration of the solution.” See Ex. 6, at 11. It is this unambiguous claim language—not Cypress’ out-of-context assessment of a single claim limitation—that must be applied when evaluating infringement by Cypress’ proposed copy of SUPREP. See *Accent Packaging*, 707 F.3d at 1327; *Unique Concepts*, 939 F.2d at 1562.

When the claims of the ’149 patent are read correctly and applied as construed by Judge Sheridan, the undisputed evidence shows that, if its ANDA is approved, Cypress will make, sell, and offer to sell “[a] **composition for inducing purgation of the colon of a patient, the composition comprising from about 100 ml to about 500 ml of an aqueous hypertonic solution**” that infringes composition claims 15 and 18. Specifically:

- Cypress’ proposed generic copy of SUPREP will be sold as a kit containing two 6-ounce bottles of solution. SF 22; BMF 52.
- The proposed labeling for Cypress’ proposed generic copy of SUPREP requires that each bottle be diluted with water to 16 ounces before administration. SF 23; BMF 53.
- When the first 6-ounce bottle of Cypress’ proposed generic copy of SUPREP is diluted with water to 16 ounces (pursuant to its proposed labeling), that bottle will contain 473 ml of an aqueous hypertonic solution. SF 27; BMF 57.
- When that first 6-ounce bottle of Cypress’ proposed generic copy of SUPREP diluted with water to 16 ounces is consumed by a patient (as is required by its proposed labeling), that solution will “induce purgation” of the patient’s colon. SF 24, 25; BMF 54-55.
- When the second 6-ounce bottle of Cypress’ proposed generic copy of SUPREP is diluted with water to 16 ounces (pursuant to its proposed labeling), that bottle will contain 473 ml of an aqueous hypertonic solution. SF 27; BMF 57.
- When that second 6-ounce bottle of Cypress’ proposed generic copy of SUPREP diluted with water to 16 ounces is consumed by a patient (as is required by its proposed labeling), that solution will “induce purgation” of the patient’s colon. SF 41; BMF 71.

Therefore, there is no dispute that, like Novel’s infringing product, Cypress’ proposed

generic copy of SUPREP will contain two infringing compositions for inducing purgation, *i.e.*, two bottles of solution that, when prepared according to Cypress' proposed labeling, necessarily will infringe claims 15 and 18 of the '149 patent. *See* Dkt. 46-15, at 1-22.

Cypress will also induce infringement of method claims 19, 20, and 23 of the '149 patent, because Cypress intends for doctors to prescribe its proposed generic product for patients to use according to its label (SF 30-32), and the label explicitly instructs users to infringe the claims of the '149 patent as described above. SF 28, 30-32, 34; BMF 59-65; *see AstraZeneca*, 633 F.3d at 1060 (finding intent to induce infringement based on the product label authorizing the patented use, which "would inevitably lead some consumers to practice the claimed method").

Cypress is wrong when it presents its puzzling argument that claim 23 supports its argument that the proposed label for its proposed generic copy of SUPREP does not induce infringement of the method claims of the '149 patent. *See* MSJ at 21. Claim 23 reads:

A method for inducing colonic purgation in a patient according to claim 20, wherein the effective amount of the composition is administered in two or more doses within a treatment period.

Dkt. 46-4, at claim 23. A person of ordinary skill in the art understands that the reference in claim 23 to "*the* effective amount of *the* composition" has antecedent basis from independent claim 15 (through claim 20), which makes clear that the term "effective amount" is the effective amount "*for inducing purgation.*" *See id.* at claims 20, 23 (emphasis added); Dkt. 46-3, at claim 15 (emphasis added). Judge Sheridan in the *Novel Case* construed "effective amount" to mean "the amount and combination of salts necessary *to produce a colonic purgation*, while not producing clinically significant electrolyte shifts." Ex. 6, at 11 (emphasis added). Therefore, claim 23 covers a method in which *the effective amount of the composition to induce purgation* (and meet all of the other limitations of claim 15) is administered two or more times within a treatment period. *See* Peura Decl. ¶¶ 73-77.

### C. Cypress' Motion Relies on an Improper Reading of the Claims

Despite the unambiguous claim language of the '149 patent, Cypress argues that “the phrase ‘about 100 ml to about 500 ml’ in the reexamined claims limits the total volume *of the claimed composition*; it does not refer to some minimum amount of solution required to induce purgation.” MSJ at 13 (emphasis in original). Cypress further argues that the “about 100 ml to about 500 ml limitation” is unbound by the functional limitation<sup>11</sup> “for inducing purgation,” and instead “refers to the total amount of solution ingested by a patient to prepare the colon for surgical or diagnostic procedures.” MSJ at 14-15. Given these assertions, it is apparent that Cypress' noninfringement argument is based on the legally and factually erroneous premise that the asserted claims of the '149 patent require “colon cleansing” rather than “purgation.” Dkt. 46-3 at claims 15 and 18; Dkt. 46-4 at claims 19-20 and 23; BMF 7-8.

Cypress' attempt to reargue the claim construction of “purgation” through the “about 100 ml to about 500 ml” limitation—despite a stipulation to Judge Sheridan's construction and repeated assertions to this Court that “[o]ur position is you don't need to construe purgation”—must be rejected. *See* Ex. 1, at 10; *see also id.* at 4 (“your Honor can decide our motion and grant the motion without addressing the issue of what purgation means”); *id.* at 22-23 (“we do not believe that the Court has to construe “purgation”).

#### 1. Cypress Ignores the Claim Limitation “for inducing purgation”

First, Cypress improperly reads the “for inducing purgation” limitation out of the claims of the '149 patent. For most of its brief, Cypress pretends that the “for inducing purgation” language does not exist. *See e.g.* MSJ at 13 (“The phrase ‘about 100 ml to about 500 ml’ in the reexamined claims limits the total volume of the claimed composition; it does not refer to some

---

<sup>11</sup> A functional limitation of a claim is one that describes “what [the invention] does rather than what it is.” *See Halliburton Energy Svcs., Inc. v. M-I LLC*, 514 F. 3d 1244, 1255 (Fed. Cir. 2008) (citing *In re Swinehart*, 439 F. 2d 210, 212 (C.C.P.A. 1971)); *see also* 3-8 Chisum on Patents § 8.04 (2013) (“functional language” is “language describing an invention in terms of what it *accomplishes* rather than in terms of what it *is*”) (emphasis in original).

minimum amount of solution required to ‘induce purgation’”) (emphasis omitted); *id.* at 14-15 (the ‘about 100 ml to about 500 ml’ limitation “refers to the total amount of solution ingested by a patient to prepare the colon for surgical or diagnostic procedures”). But claim language must be read as a whole and individual claim limitations cannot be ignored or taken out of context. *See, e.g., Accent Packaging*, 707 F.3d at 1327; *Unique Concepts*, 939 F.2d at 1562. When the claims of the ’149 patent are read in their entirety, and Judge Sheridan’s claim construction is applied, there is no dispute that the claimed compositions of “about 100 ml to about 500 ml” are “*for* inducing purgation,” not colon cleansing. *See* Ex. 6, at 6; Dkt. 46-15, at 1-22; BMF 7-8.

2. Claims Must be Read from the Perspective of a Person of Ordinary Skill in the Art of the ’149 Patent, Not That of Cypress’ Attorneys

Second, Cypress argues that the “about 100 ml to about 500 ml” limitation “is “readily understandable and should be accorded the same plain and ordinary meaning by which it was understood during prosecution.” MSJ at 14. While it is axiomatic that claims must be viewed from the perspective of a person of ordinary skill in the art, *e.g., Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, 1361 n.3 (Fed. Cir. 2008); *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc), Cypress does not evaluate the claims from that perspective.<sup>12</sup> Instead, Cypress offers only attorney argument that the phrase “about 100 ml to about 500 ml”—an unambiguous reference to volume—actually “refers to the total amount of solution ingested by a patient to prepare the colon for surgical or diagnostic procedures.” MSJ 14-15. Cypress is wrong.

A person of ordinary skill in the art of the ’149 patent does not read the claims of the ’149 patent like Cypress’ attorneys. Dr. David Peura, Braintree’s expert in the *Novel Case*

---

<sup>12</sup> Cypress has not offered any expert evidence on the perspective of a person of ordinary skill in the art. Cypress has admitted as much: “I am trying ... to imagine what I would put in as an expert report in this case, and I can’t imagine anything that I would have an expert say.” *See* Ex. 1, at 10; *see also id.* at 16 (“frankly, I can’t conceive of what we would say in an expert report”). Resort to the plain and ordinary meaning, and stipulated meaning, of the claim terms is not a substitute for how one of ordinary skill in the art would read the claims as a whole.

whom Judge Sheridan found credible (*see e.g.* Ex. 5, at 40 (*Novel Case Opinion on Validity*)), is a person of ordinary skill in the art of the '149 patent. *See* Peura Decl., ¶¶ 5-12. In Dr. Peura's opinion, "a person of ordinary skill in the art would understand that the purpose of the claimed 'composition' is 'for inducing purgation.'" Peura Decl., ¶ 61. Therefore, a person of ordinary skill in the art would read the "about 100 ml to about 500 ml" limitation together with the requirement that the composition is "for inducing purgation." Peura Decl., ¶¶ 61-63. Cypress' attorney argument—unsupported by any expert—is not only inconsistent with the unambiguous claim language, but also with how that language would be understood by a person of ordinary skill in the art. For these reasons alone, Cypress' argument should be rejected and its motion denied. *Sundance*, 550 F.3d at 1361; *Estee Lauder Inc. v. L'Oreal, S.A.*, 129 F.3d 588, 595 (Fed. Cir. 1997) ("arguments of counsel cannot take the place of evidence lacking in the record") (internal citation omitted).

3. Cypress Seeks to Import a Nonexistent "Colon Cleansing" Limitation into the Claims

Third, Cypress seeks to import a nonexistent "colon cleansing" limitation into the phrase "about 100 ml to about 500 ml" based on the specification of the '149 patent. MSJ at 4-5, 14-15. This is improper. *See Phillips*, 415 F.3d at 1323 (noting that one may not "import[] limitations from the specification into the claims"). It is the claim language—not the specification—that defines the invention. *Id.* at 1312 ("It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude.") (internal quotations omitted). As discussed above, the claims of the '149 patent define the invention as a composition with a recited volume range "for inducing purgation," which is something less than complete colon cleansing. *See supra* at Section III.C.1.

Moreover, Judge Sheridan rejected Cypress' *very argument* when he explained that

“[a]lthough cleansing is a term used in the specification of the ’149 Patent, *claims 15 and 18 clearly adopt purgation as the methodology to improve visualization of the colon.*” *See* Ex. 6, at 6 (emphasis added); BMF 85. Judge Sheridan reasoned that although there are references to “cleansing” in the specification, “the term ‘cleanse’ is never used in the language of claims 15 and 18.” *See id.* at 5-6; BMF 84. “Hence, when enumerating the claims, the inventors were being more precise with their use of ‘purgation.’” *See id.*

In other words, the claims of the ’149 patent define an invention that uses induced purgation to achieve the goal of colon cleansing. But the claims do not require a product to achieve colon cleansing for infringement to occur. *See* Dkt. 46-15, at 16 (“As this Court recognized in its Claim Construction Order, purgation is the method to achieve the goal of colon cleansing.”).

Cypress’ reliance on the experimental solutions A-E described in the specification is a misguided attempt to limit the claims to disclosed embodiments. MSJ at 4-5. Solutions D and E are “preferred embodiments,” and the patent expressly states that those embodiments were “not intended to limit the present invention to the specific formulations shown and described.” *See* Dkt. 46-4, ’149 patent, at Col. 11:55-63. Even absent this statement in the ’149 patent, it is improper to limit claim language based on embodiments described in the specification. *Falana v. Kent State Univ.*, 669 F.3d 1349, 1355 (Fed. Cir. 2012) (“[A] court may not import limitations from the written description into the claims.”) (internal quotations omitted); *Innova/Pure Water, Inc. v. Safari Water Filtration Sys.*, 381 F.3d 1111, 1117 (Fed. Cir. 2004).<sup>13</sup>

---

<sup>13</sup> Cypress tries to distract this Court from its clear infringement of the ’149 patent by arguing the extraneous fact that the volume of SUPREP is different from the volume of the solutions that were tested in the study described in the ’149 patent specification. *See* MSJ at 4-5. As Dr. Cleveland explains in his declaration, this change was made when the commercial product was developed so that the drug would be palatable and so that the salts would remain dissolved in solution. *See* Declaration of Mark Cleveland, Ph.D. in Support of Braintree’s Opposition to Cypress’ Motion for Summary Judgment of Noninfringement (“Cleveland Decl.”), at ¶¶ 5-12. This difference in volume has nothing to do with the issue of infringement. Cypress’ discussion of it is nothing more than a red herring.

Cypress' argument for importation of a "cleansing" limitation into the claims, based on Braintree's alleged "admissions" or "representations to the USPTO and to the public" (*see* MSJ at 8), was also rejected in the *Novel Case*. After considering extensive claim construction briefing and holding a two-day *Markman* hearing with expert testimony, Judge Sheridan correctly determined that "these alleged admissions do nothing to contradict the fact that . . . one bottle of SUPREP is sufficient to cause purgation of the colon." *See* Dkt. 46-15, at 16-17.

Judge Sheridan's logic applies equally here. None of the alleged "admissions" presented by Cypress (many of which are irrelevant and taken out of context<sup>14</sup>) change the indisputable fact that the claimed compositions of the '149 patent are for purgation, the inventors' chosen "methodology to improve visualization of the colon." *See* Ex. 6, at 6. Cypress' attempt to import "cleansing" into the claims based on selective snippets from the prosecution history should be rejected.<sup>15</sup>

4. Cypress' Reading of the Claim Improperly Renders the Claim Limitation "for inducing purgation" Meaningless

Fourth, Cypress' reading of "about 100 ml to about 500 ml" must be rejected because it would render the claim language "for inducing purgation" meaningless. *See Douglas Dynamics, LLC v. Buyers Prods. Co.*, 717 F.3d 1336, 1350 (Fed. Cir. 2013) (rejecting proposed construction that would render claim terms "superfluous"); *Mangosoft, Inc. v. Oracle Corp.*, 525 F.3d 1327, 1330 (Fed. Cir. 2008) (same). Cypress' argument that "about 100 ml to about 500 ml" refers to colon "cleansing" ignores the claim term "for inducing purgation." As Judge Sheridan recognized, purgation is the inventors' chosen methodology to achieve colon cleansing;

<sup>14</sup> *See* Braintree's Responses to Cypress' Rule 56.1 Statement, at Responses to Facts Nos. 23-31.

<sup>15</sup> As part of its attempt to distract this Court from the plain evidence of infringement, Cypress mentions Braintree's Request for Patent Term Extension in its motion. *See* MSJ at 7-8. Due to a miscommunication between Braintree and the patent attorney who worked on the patent term extension, the request was first filed on the original '149 patent claims. When the patent attorney became aware of the mistake, she filed a Supplemental Request for Patent Term Extension on the reexamined claims.

purgation therefore must be something less than colon cleansing. Reading “about 100 ml to about 500 ml” to require complete cleansing—when the inventors chose to claim a composition that caused something less than cleansing—would make the narrower functional limitation “for inducing purgation” superfluous.

5. Cypress Improperly Attempts to Reargue the Claim Construction of “Purgation”

Fifth, Cypress’ attempt to import a “cleansing” limitation into the claims must be rejected for what it plainly is—an improper attempt to have “purgation” mean “cleansing.” If Cypress does not read “for inducing purgation” out of the claims of the ’149 patent (as it attempts to do), its only remaining argument is that “purgation” means “cleansing.” But Cypress cannot make that argument. Not only is it foreclosed by Judge Sheridan’s claim construction in the *Novel Case*, but Cypress’ counsel has *agreed* not to dispute that construction for purposes of its motion. See Dkt. No. 41 at ¶¶ 3, 5.<sup>16</sup> However, that is exactly what Cypress has done in its motion.

Because Cypress can only prevail on summary judgment if: (1) purgation is improperly read out of the claims; (2) cleansing is improperly imported into the claims; or (3) “purgation” is construed to mean cleansing, Cypress’ motion must be denied.<sup>17</sup>

**D. Cypress’ Noninfringement Argument Relies on a Mischaracterization of its Proposed Generic Copy of SUPREP and its Proposed Indication**

Cypress argues that its proposed product does not meet the “about 100 ml to about 500 ml” limitation of the claims of the ’149 patent because it “will be administered as 946 ml of

<sup>16</sup> Judge Sheridan reasoned that “the term ‘cleanse’ is never used in the language of claims 15 and 18.” See Ex. 6, at 6 (Novel Case Order on Claim Construction). “Hence, when enumerating the claims, the inventors were being more precise with their use of ‘purgation.’” See *id.*

<sup>17</sup> To the extent the Court believes construction of “purgation” is necessary to resolve Cypress’ motion, the case must be resolved in Braintree’s favor. Cypress has conceded that if “if you rule against us on [the issue of the need to construe purgation], we have essentially given up the field of battle to Mr. Regan on the issue of purgation. So if he persuades you that purgation does need to be construed, then we will lose.” See Ex. 1, at 10:18-20 (June 10, 2013 Hearing Transcript); see also *id.* at 10:7-13 (“we are either right on the issue that you do not need to construe purgation, or we lose; that is, you find that there is infringement.”); *id.* at 12 (“if you allow us to file the motion and you rule against us on purgation – that is, you find that construing that claim term is something necessary for resolution of the case – we’re done”).

aqueous solution.” *See, e.g.*, MSJ at 1, 2, 15 (emphasis added). This is an inaccurate and misleading description of Cypress’ proposed product. The undisputed evidence is that Cypress’ proposed generic copy of SUPREP will *never* be administered to a patient as 946 ml of solution; indeed, such an administration would be contrary to the proposed label Cypress submitted to the FDA. *See* Dkt. 46-1, at CYPRESS000007-8. Instead, like SUPREP and Novel’s infringing copy, Cypress’ proposed generic will be taken in two *separate* 473 ml administrations which are separated by a 10-12 hour period. *See supra* at Section III.B; SF 34-35; BMF 51-73. Each 473 ml administration is designed to and will induce purgation. SF 24-27; BMF 55, 57, 71.

Not only does Cypress mischaracterize how its product will be administered to patients, it misstates the product’s proposed indication. Cypress argues that “[n]othing in the proposed labeling provides any motivation for a patient to take less than the full 946 ml dosage in order to induce diarrhea in a manner short of the sole listed indication—*colonic purgation* required in preparation for colonoscopy.” MSJ at 21 (emphasis added). But the indicated use for Cypress’ proposed generic copy of SUPREP is not “colonic purgation.” The FDA-approved indication for SUPREP, and the indication Cypress seeks for its generic copy, is “*cleansing* of the colon as a preparation for colonoscopy.” SF 4, 20. As Judge Sheridan recognized, cleansing is the ultimate goal when a patient is prescribed SUPREP—purgation, induced by each 473 ml administration of SUPREP, is the mechanism used to achieve that goal. *See* SF 28; Dkt. 46-1, at CYPRESS0000004; *see also* Ex. 6, at 6. Cypress’ misleading statement that a patient must consume 946 ml of its generic product for “colonic purgation” is yet another improper attempt

by Cypress to equate “cleansing” with “purgation.”<sup>18</sup>

#### E. Cypress’ Misapprehends Infringement Under §271(e)

In Hatch-Waxman litigation, “the substantive determination whether actual infringement or inducement will take place *is determined by traditional patent infringement analysis*, just the same as it is in other infringement suits, including those in a non-ANDA context.” *Warner-Lambert*, 316 F.3d at 1365 (emphasis added). Cypress’ motion suggests otherwise – that infringement under §271(e)(2)(A) is different, requiring the proposed generic product to be compared “as a whole” (Cypress’ characterization) to the asserted patent’s claims. MSJ at 9, 16.

Cypress is wrong. There is no case law holding that infringement of composition claims under §271(e)(2)(A) is necessarily determined by comparing the asserted claims to the *total* amount of a drug required for an approved indication. To the contrary, the Federal Circuit has held that comparing the asserted claims to “[w]hat is likely to be sold, or, preferably, what will be sold, will ultimately determine whether infringement exists.” *Glaxo v. Novopharm*, 110 F.3d at 1569-70 (rejecting patentee’s argument that §271(e)(2)(A) infringement action requires a unique infringement analysis focused solely on the ANDA); *see also Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1248-49 (Fed. Cir. 2000).

Here, Cypress will sell a kit containing two bottles of generic SUPREP that, when diluted according to the product’s label, will infringe claims 15 and 18 of the ’149 patent by, among other things, inducing purgation in a patient. *See supra* at Section III.B; BMF 20, 34, 42-46, 55-

---

<sup>18</sup> In its mistaken argument that the infringement determination is focused solely on the ANDA, and that SUPREP can *only* be considered as a 946 ml solution for purposes of patent coverage, Cypress conflates the separate regimes of FDA regulatory law and patent law. FDA regulatory law is concerned with safety and efficacy. *See, e.g.*, Federal Food, Drug and Cosmetic Act of 1938, 21 U.S.C. §355 (granting the Secretary of Health and Human Services the responsibility for approval of safe and effective drugs); 21 C.F.R. Part 5 (delegating that authority to FDA). Consequently, Cypress’ ANDA and product label direct a patient to ingest two diluted bottles of the proposed product, 10 to 12 hours apart, to achieve colon cleansing safely and efficaciously. *See* Dkt. 46-1, at CYPRESS000007. Patent infringement, by contrast, is determined by comparing the accused product against the patent claims. *Warner-Lambert*, 316 F.3d at 1365-66. Cypress’ proposed product, by the separate administration of each of its bottles, meets the limitations of the asserted claims of the ’149 patent’s composition claims and directs patients to practice its asserted method claims. *See* BMF 100. Nothing more is required for infringement. *See id.*

59, 71, 74-77. The total volume of SUPREP required for the FDA-approved indication is not relevant to Cypress' infringement of those claims. *See, e.g., Glaxo v. Novopharm*, 110 F.3d at 1569 ("a district court's inquiry in a suit brought under § 271(e)(2) is the same as it is in any other infringement suit.").<sup>19</sup>

#### **F. Judge Sheridan Properly Defined Novel's Accused Product**

Cypress' main argument for why Judge Sheridan's thoughtful determinations in the *Novel Case* should be discredited is that Judge Sheridan "incorrectly defined the 'Generic Product'" in his infringement analysis as a composition of "about 100 ml to about 500 ml." MSJ at 9. This is incorrect and based on a mischaracterization of Judge Sheridan's opinion. In his opinion, Judge Sheridan defined the "Generic Product" as: "Novel's proposed generic version of the SUPREP drug product is named Sodium Sulfate, Potassium Sulfate, and Magnesium Sulfate Oral Solution (the Generic Product)." Dkt. 46-15, at 6. Judge Sheridan correctly stated that "Novel's copy of SUPREP requires that a patient ingest 'two bottles of oral solution'." *Id.* at 17. Judge Sheridan did not, as Cypress misstates, define Novel's product as a composition of about 100 ml to about 500 ml. MSJ at 9.

In the language Cypress quotes from Judge Sheridan's opinion, Judge Sheridan stated that "there is no genuine dispute that the Generic Product *constitutes* a composition of from about 100 ml to about 500 ml." Dkt. 46-15 at 17 (emphasis added); MSJ at 9. The word "constitutes" means to "make up, form, compose." *See, e.g.,* <http://www.merriam-webster.com/dictionary/constitute>. Therefore, Cypress' conclusion that Judge Sheridan, in this

---

<sup>19</sup> A different interpretation could lead to the bizarre scenario where there is no infringement under §271(e), but infringement would occur under §271(a) *after* a generic product is actually made, used or sold in the United States. This simply cannot be the law, because it would frustrate Congress' intent of providing an expedited infringement remedy for NDA holders (like Braintree) in exchange for the savings in time and money that ANDA applicants (like Cypress) achieve from using the NDA holders' clinical study data. *See, e.g., Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676-77 (1990) (describing the streamlined ANDA approval process and the "important new mechanism" of §271(e)(2) infringement "designed to guard against infringement of patents relating to pioneer drugs").

statement, defined the “Generic Product” as one diluted bottle is mistaken. Judge Sheridan simply explained that Novel’s proposed copy of SUPREP—like Cypress’ generic copy— infringes the composition claims of the ’149 patent because the product includes a 473 ml bottle of solution for inducing purgation. *See* Dkt. 46-15, at 16-17.

**G. Braintree’s Infringement Argument Does Not Improperly Divide the Accused Product**

Cypress argues that Braintree improperly divides the accused product by “artificially ‘carv[ing] out a portion’ of the accused product in an attempt to show infringement of a claimed range.” MSJ at 2, 17-18. This argument misapplies the law. The “carve out” language in *Jeneric/Pentron, Inc. v. Dillon Co.*, 205 F.3d 1377 (Fed. Cir. 2000), relied upon by Cypress, stands for the unremarkable proposition that a patentee may not import a functional limitation into asserted claims “[w]here the function is not recited in the claim itself by the patentee.” *Ecolab, Inc. v. Envirochem, Inc.*, 264 F.3d 1358, 1367 (Fed. Cir. 2001).<sup>20</sup>

The District Court for the District of Delaware has further explained that the purpose of the “carve out” language in *Jeneric/Pentron* is to prohibit an “attempt to artificially decompose a single ... component into sham sub-components.” *Dow Chem. Co. v. NOVA Chem. Corp.*, 629 F. Supp. 2d 397, 408 (D. Del. 2009) (Farnan, D.J.) (finding *Jeneric/Pentron* inapplicable because the division of the accused product into “unique polymer components” was not a sham because the patent claims referenced the “possibility of multiple unique polymer components”).

*Jeneric/Pentron*’s “carve out” holding is inapplicable here. Braintree’s infringement argument does not import a functional limitation into the asserted claims of the ’149 patent, nor does it decompose a single component into ***sham sub-components***. *See Ecolab*, 264 F.3d at

---

<sup>20</sup> A court in this district has similarly interpreted the “carve out a portion” language in *Jeneric/Pentron* to proscribe importing functional limitations into patent claims. *See Novartis Pharms. Corp. v. Apotex Corp.*, No. 02CIV.8917 (KMW)(HBP), 2006 WL 626058 at \*8 (S.D.N.Y. Mar. 13, 2006) (Pitman, U.S.M.J.).

1367; *Dow Chem.*, 629 F. Supp. 2d at 408. Rather, Braintree’s infringement position relies on an *express claim term*: “for inducing purgation.” Separately evaluating, as Judge Sheridan did, each of the two 473 ml bottles of solution sold as part of Cypress’ proposed generic product because each will induce purgation, does not constitute “artificially decompos[ing] a single . . . component into sham sub-components.” *See Dow Chem.*, 629 F. Supp. 2d at 408.<sup>21</sup>

Cypress attempts to press the facts of this case into *Jeneric/Pentron*’s mold, by contending that “Braintree attempts to argue that only a portion of Cypress’ ANDA Product acts to ‘induce purgation,’ while the additional volume ingested by the patient performs some other undefined function.” MSJ at 17.<sup>22</sup> Braintree has never argued that the additional volume performs “some other undefined function.” This is a fabricated account of Braintree’s position. Just as in the *Novel Case*, Braintree’s position is that the second 473 ml diluted bottle of solution—taken 10 to 12 hours after the first bottle, as per Cypress’ proposed label—induces additional purgation, as Cypress has stipulated.<sup>23</sup> *See* SF 24-26, 41; BMF 71. Thus, *each* bottle that Cypress intends to make and sell, when prepared according to the product’s proposed label, will infringe the composition claims of the ’149 patent, not just the first bottle.<sup>24</sup>

#### H. Cypress’ Assertion that Purgation is an “Off-Label” Use Lacks Merit

Cypress uses the *Warner-Lambert* case and its progeny to argue that its proposed generic

<sup>21</sup> For these reasons, Cypress’ example of a 15mg pill being split in half makes no sense.

<sup>22</sup> Although heavily cited by Cypress, *Jeneric/Pentron* did not address infringement by an ANDA applicant.

<sup>23</sup> *Jeneric/Pentron* is further distinguishable on its facts. The claims there were directed to a porcelain dental composition containing 0-1% of cerium oxide. Although the accused product contained 1.61% cerium oxide, outside the claimed range, the patentee maintained that it infringed because a 0.69% portion of its cerium oxide served a different function from that discussed in the patent specification. Because the patentee’s only infringement argument was that a portion of cerium oxide *contained in any sample of the accused product* should be disregarded, the court rejected this as an “attempt to carve out a portion” of the accused product. *See Jeneric/Pentron*, 205 F.3d at 1382-83. By contrast, nothing in Cypress’ individual 473 ml bottle of diluted solution is disregarded: each bottle in Cypress’ proposed kit meets every limitation of and infringes the asserted composition claims.

<sup>24</sup> It is Cypress, not Braintree, that runs afoul of clear Federal Circuit precedent by urging this Court to do the—equally prohibited—inverse of the prohibited conduct in *Jeneric/Pentron*. As explained above at Section III.C., Cypress argues that this Court should read the functional claim limitation “for inducing purgation” out of the asserted claims. *See Accent Packaging*, 707 F.3d at 1327; *Unique Concepts*, 939 F.2d at 1562; *Perkin-Elmer Corp. v. Westinghouse Elec. Corp.*, 822 F.2d 1528, 1532-33 (Fed.Cir.1987) (holding that all the limitations of a claim must be considered meaningful).

copy of SUPREP does not meet the volume limitation of the '149 patent claims because the only approved, “on-label” use for its proposed product is colon cleansing—not purgation. MSJ at 11-12, 19-21. Cypress’ argument fails because “purgation” and colon “cleansing” are not two distinct uses for SUPREP, one of which is off-label. Instead, purgation is the *mechanism* to achieve the *goal* of colon cleansing, which is the FDA-approved indication. *See* Dkt. 46-15, at 33-34; Ex. 6, at 6. Without purgation, colon cleansing is not possible. SF 8 (“SUPREP cleanses the colon of a patient by inducing copious, watery diarrhea”).

It is indisputable that two bottles of SUPREP (and Cypress’ generic copy) cannot be administered without administration of each individual bottle. Administration of one bottle of SUPREP cannot logically be an off-label use where the FDA-approved label itself requires that SUPREP be administered in a split-dose regimen—one bottle at a time. SF 34-36, 34, 41. Cypress’ proposed label instructs its patients to take one 473 ml bottle of diluted solution the evening before the colonoscopy, and a second 473 ml bottle of diluted solution the day of the colonoscopy. *See* Dkt. 46-1, at CYPRESS000007-8; SF 34. Each 473 ml bottle of diluted solution induces a purgation. SF 24-26, 41.

Accordingly, if approved by FDA, Cypress will make and sell a composition of “about 100 ml to about 500 ml” for inducing purgation. Cypress’ argument amounts to the nonsensical assertion that its label instructs patients to consume its product *off*-label twice in order to use the product “on-label” for its approved indication. The reality is simpler: the administration of Cypress’ generic product as described in its proposed label—administration of two 473 ml bottles 10 to 12 hours apart—leads to two distinct instances of infringement. For these reasons, Cypress’ motion for summary judgment should be denied. Dkt. No. 41 ¶3; *see* Peura Decl., ¶ 78.

1. The Cases Cypress Cites Are Inapposite

The law Cypress cites to support its “off-label” argument is inapplicable here. As an

initial matter, most of these cases relate to method-of-treatment claims only, where the claims at issue covered specific *uses* of a drug to treat disease, not the drug *composition* itself. *See Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316, 1319 (Fed. Cir. 2012); *AstraZeneca LP*, 633 F.3d at 1048, 1057; *Allergan v. Alcon Labs.*, 324 F.3d 1322, 1323 (Fed. Cir. 2003); *Warner-Lambert*, 316 F.3d at 1352. As Judge Sheridan correctly determined, these holdings provide “no guidance” with respect to drug composition claims, such as two of the claims at issue in this case—claims 15 and 18. *See* Dkt. 46-15, at 16 (*Novel Case* Summary Judgment Opinion).

But even as to Braintree’s asserted method claims, the cases are inapposite. *Bayer-Schering*, *Allergan*, and *Warner-Lambert* all stand for the proposition that “a method of use patent holder may not sue an ANDA applicant for induced infringement of its patent, if the ANDA applicant is not seeking FDA approval for the use claimed in the patent and if the use claimed in the patent is not FDA-approved.” *Allergan*, 324 F.3d at 1332-33 (citing *Warner-Lambert*, 316 F.3d at 1354-55); *see also Bayer-Schering*, 676 F.3d at 1320-21. In other words, these cases hold that an ANDA applicant cannot induce infringement of claims if its proposed label does not require patients and doctors to practice a claimed method.

In each of these three cases, the NDA holder asserted infringement of a patent for an indication that was not FDA-approved, while the ANDA holder sought approval to market the drug for an entirely different FDA-approved indication. In each case, it would have been *illegal* for the ANDA applicant to market a product for the purpose claimed in the patent-in-suit,

because the applicant did not seek FDA permission to make and sell such a product.<sup>25, 26</sup>

Naturally, infringement—which focuses on the product the ANDA applicant will likely market—was not found. As the Federal Circuit succinctly stated in *Warner-Lambert*:

Here, the request to make and sell a drug labeled with a permissible (non-infringing) use cannot reasonably be interpreted as an act of infringement (induced or otherwise) with respect to a patent on an unapproved use, ***as the ANDA does not induce anyone to perform the unapproved acts required to infringe.***

*Warner-Lambert*, 316 F.3d at 1364-65 (emphasis added).

There are no such facts here. Patients and doctors following the instructions in Cypress’ proposed label *must* infringe method claims 19, 20, and 23 of the ’149 patent. *See supra* at Section III.B. Cleansing is the FDA-approved indication for SUPREP, as well as the indication sought by Cypress for its proposed generic copy. *See* SF 4, 20. Purgation is a mechanism to achieve cleansing. *See* Ex. 6, at 6; Dkt. 46-15, at 33-34; SF 8, 21, 25. To use Cypress’ generic product for cleansing, that product must first induce a purgation. SF 21, 24-26, 41. In other words, when a patient uses Cypress’ copy of SUPREP for the approved indication of colon cleansing, it necessarily will infringe the method claims of the ’149 patent.

Cypress cites a single case, *Bayer AG*, 212 F.3d 1241, for the proposition that the principles of *Warner-Lambert* apply to composition claims. MSJ at 13. Cypress’ counsel argued that *Bayer AG* stands for the proposition that “[a]ll we have to look at in an ANDA case is the ANDA itself. It will tell us all we need to know because the ANDA defines the product.” *See* Ex. 1, at 12. Once again, Cypress misreads and misstates the law.

---

<sup>25</sup> *See Bayer-Schering*, 676 F.3d at 1326 (finding no infringement where patent covered use of drug simultaneously for non-FDA-approved antiandrogenic and anti-mineralocorticoid effect, and approved contraceptive effect, while ANDA filer sought approval only for contraceptive effect); *Allergan*, 324 F.3d at 1327-28, 1334 (finding no infringement where patent covered non-FDA approved use of drug for protection of optic nerve and neural protection, while ANDA filer sought approval for FDA-approved use of drug to reduce intraocular pressure); *Warner-Lambert*, 316 F.3d at 1351-52, 1366 (finding no infringement where patent covered non-FDA-approved use of drug for treatment of neurodegenerative disease, while ANDA filer sought approval for FDA-approved use of drug for treatment of epilepsy).

<sup>26</sup> *See, e.g., Bayer AG*, 212 F.3d at 1249-50 (cataloging the severe civil and criminal sanctions for marketing a drug not approved by the FDA, or for failing to adhere to the specifications disclosed in the ANDA).

In *Bayer AG*, the generic defendant would never practice the claims of the patent-in-suit because the ANDA and the patent claims recited mutually exclusive, non-overlapping compositions. *Bayer AG*, 212 F.3d at 1249-50. The patent-in-suit claimed a solid composition containing crystals with a “specific surface area” (“SSA”) within the range of 1.0 to 4 m<sup>2</sup>/g. *Bayer AG*, 212 F.3d at 1246. The defendant’s ANDA specified that its proposed product would have an SSA of 5 m<sup>2</sup>/g or greater. *Id.* at 1246, 1249. Given that the ANDA controls the composition of the product, the Federal Circuit, focusing on the “product that will be sold,” held that the proposed generic product did not infringe because, if approved by FDA, it would not (and could not) have the claimed SSA. *See id.* at 1249-50.

Despite Cypress’ assertion to the contrary, *Bayer AG* is inapposite because volume, unlike SSA, is a property of a composition *in the aggregate*. Unlike in *Bayer AG*, Cypress’ generic of copy of SUPREP, prepared according to its ANDA, will meet every limitation of the asserted composition claims of the ’149 patent, including the “about 100 ml to about 500 ml” limitation. Each 473 ml bottle of diluted solution, prepared according to Cypress’ ANDA, is a composition of “about 100 ml to about 500 ml” “for inducing purgation.” *See supra* at Section III.C.1.

2. Judge Sheridan Rejected Cypress’ On-/Off-Label Argument in the *Novel Case*

Novel argued, as Cypress does here, that administration of one diluted bottle of SUPREP to cause purgation is an “off-label use,” and therefore cannot infringe the claims of the ’149 patent under *Warner-Lambert* and its progeny. *See* Dkt. 46-15, at 16 (*Novel Case Summary Judgment Opinion*). Judge Sheridan held that this argument was “without merit,” stating: “***Because purgation is the method by which SUPREP achieves the FDA-approved indication of colon cleansing, purgation cannot be an off-label use for SUPREP.***” *Id.* (emphasis added).

Judge Sheridan further reasoned:

Novel's argument is akin to an assertion that using an asthma medication that improves breathing is off-label if it works by reducing airway inflammation; reduction of airway inflammation is the ***method by which the medication achieves the goal*** of improved breathing. The cases Novel cites in support of its assertion ***do not involve methods to achieve an FDA-approved indication, and are therefore inapplicable***. The cases also relate to method of use claims only—in each case, the claims at issue covered specific uses of a drug to treat disease, not the drug composition itself. *See Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316, 1319 (Fed. Cir. 2012); *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1048, 1057 (Fed. Cir. 2010); *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1352 (Fed. Cir. 2003); *Allergan v. Alcon Labs.*, 324 F.3d 1322, 1323 (Fed. Cir. 2003). ***These cases provide no guidance to the Court*** with respect to drug composition claims, such as claims 15 and 18, as nothing in the cited cases addresses the fact that here, Novel intends to make, offer to sell, and sell a product that directly infringes the '149 patent.

*Id.* (emphasis added); *see also* Ex. 6, at 6 (*Novel Case Order on Claim Construction*) (finding that “claims 15 and 18 clearly adopt purgation as the methodology to improve visualization of the colon”). This Court should reject Cypress' argument for the same reasons that Judge Sheridan rejected Novel's parallel argument.

#### IV. CONCLUSION

For the reasons stated above, Braintree respectfully requests that this Court: (1) deny Cypress' Motion for Summary Judgment of Noninfringement; and (2) enter judgment against Cypress and for Braintree that Cypress and its ANDA Product infringe asserted claims 15, 18, 19, 20, and 23 of the '149 patent. *See* Dkt. 41, ¶ 3; Ex. 1, at 10:7-13 (June 10, 2013 Hearing Tr.); Braintree's Proposed Order, filed concurrently herewith.

Dated: August 2, 2013

/s/ John J. Regan

John J. Regan

Jennifer C. Brown

WILMER CUTLER PICKERING

HALE AND DORR LLP

60 State Street

Boston, MA 02109

(617) 526-6000

Christopher R. Noyes

WILMER CUTLER PICKERING

HALE AND DORR LLP

7 World Trade Center

250 Greenwich Street

New York, NY 10007

(212) 230-8800

*Attorneys for Plaintiff*

*Braintree Laboratories, Inc.*

**CERTIFICATE OF SERVICE**

I hereby certify that on August 2, 2013, a true and correct copy of the foregoing BRAINTREE LABORATORIES INC.'S OPPOSITION TO DEFENDANT CYPRESS PHARMACEUTICAL, INC.'S MOTION FOR SUMMARY JUDGMENT OF NONINFRINGEMENT was filed through the Court's Electronic Filing System (ECF), and was served electronically to the registered participants as identified on the Notice of Electronic Filing (NEF).

Dated: August 2, 2013

/s/ John J. Regan